HALEON

Panadol Sinus Caplets
PATIENT INFORMATION LEAFLET

Each caplet contains:

Paracetamol 500 mg
Pseudoephedrine Hydrochloride 30 mg

Other Ingredients: Talc-Purified, Povidone, Starch-Pregelatinised maize, Sodium benzoate, Starch-Maize, Stearic acid

What is Panadol Sinus and what is it used for?

Panadol Sinus is a white caplet contains Paracetamol which is an Analgesic and Antipyretic and Pseudoephedrine which is a nasal decongestant.

For the temporary relief of sinus congestion and pain, nasal congestion and runny nose.

Also it is used for relief of fever, headache and body aches.

How to take Panadol Sinus?

For Oral administration only.

Adults and children aged 12 years and over:

- 2 caplets to be taken orally every 6 hours but do not take more than 8 caplets in 24hours.
- Consult your doctor if symptoms persist for more than 7 days.
- Don't take for more than a few days at a time except on medical advice.
- Do not exceed the stated dose or frequency of dosing.
- Minimum dosage interval: 6 hours
- Should not be used for more than 48 hours for children aged 12 – 17 except on medical advice.
- Do not use in children under the age of 12 years.

Before You Take Panadol Sinus

a. Do not use Panadol Sinus if:

- You have previous history of hypersensitivity to paracetamol, pseudoephedrine, or any of the other ingredients of Panadol Sinus.
- You have severe hypertension or severe coronary artery disease.
- You are taking other sympathomimetics (such as decongestants, appetite suppressants, and amphetamine-like psychostimulants).
- You are taking or have taken in the past 2 weeks drug named MonoAmine Oxidase inhibitors (MAOIs) as it may lead to hypertensive crisis.
- You have severe renal impairment.

b. Take special care with Panadol Sinus if:

You should consult your doctor before taking this product if:

- You have liver impairment or mild to moderate kidney impairment.
- You have cardiovascular disease, arrhythmia, hypertension, hyperthyroidism, prostatic enlargement, diabetes, glaucoma or phaeochromocytoma.
- If you are taking beta-blockers or other antihypertensives.
- You have glutathione depleted states such as sepsis or you have a severe infection as the use of Paracetamol may increase the risk of metabolic acidosis. Signs of metabolic acidosis include:
- Deep, rapid, difficult breathing, feeling sick (nausea), being sick (vomiting), Loss of appetite
- Caution is advised if paracetamol is administered concomitantly with flucloxacillin due to increased risk of high anion gap metabolic acidosis (HAGMA), particularly in patients with severe renal impairment, sepsis, malnutrition and other sources of glutathione deficiency (e.g. chronic alcoholism), as well as those using maximum daily doses of paracetamol. Close monitoring, including measurement of urinary 5-oxoproline, is recommended.
- Contact a doctor immediately if you get a combination of these symptoms.
- There have been reports of ischaemic colitis with Pseudoephedrine. Pseudoephedrine should be discontinued immediately and medical advice sought if sudden abdominal pain, rectal bleeding or other symptoms of ischaemic colitis develop.
- There have been rare cases of posterior reversible encephalopathy (PRES)/reversible cerebral vasoconstriction syndrome (RCVS) reported with sympathomimetic drugs, including pseudoephedrine. Symptoms reported included sudden onset of severe headache, nausea, vomiting, and visual disturbances. Most cases improved or resolved within a few days following appropriate treatment. Pseudoephedrine should be discontinued, and medical advice sought immediately, if signs/symptoms of PRES/RCVS develop.

There have been reports of acute systemic vasoconstrictive events with pseudoephedrine. Significant examples include:

- Acute Coronary Syndrome (ACS): Symptoms include sudden chest pain, tightness, heavy sweating and dyspnoea at rest.
  Ischaemic colitis: Symptoms include sudden abdominal pain and rectal bleeding.
- Posterior reversible encephalopathy (PRES)/reversible cerebral vasoconstriction syndrome (RCVS): Symptoms included sudden onset of severe headache, nausea, vomiting, and visual disturbances. Most cases improved or resolved within a few days following appropriate treatment.
  Pseudoephedrine should be discontinued immediately and medical advice sought if any signs/symptoms vasoconstrictive events develop.

- If you experience sudden severe headache.

* This product contains 0.6 mg Sodium benzoate per tablet to be taken into consideration by patients on controlled Sodium diet.

* This product contains Paracetamol and Pseudoephedrine. Do not use with other products containing paracetamol or decongestants products including cough and cold preparations.

* Keep medication out of sight and reach of children.

* Please see your doctor if your symptoms persist, do not improve, worsen or new symptoms occur.

C. Taking other medications:

- The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular daily use of paracetamol-containing products with increased risk of bleeding; occasional doses have no significant effect.
- Paracetamol absorption is increased by substances that increase gastric emptying, e.g. metoclopramide
- Paracetamol absorption is decreased by substances that decrease gastric emptying e.g. propantheline, antidepressants with anticholinergic properties, and narcotic analgesics
- Paracetamol may increase chloramphenicol concentrations
- The risk of paracetamol toxicity may be increased in patients receiving other potentially hepatotoxic drugs or drugs that induce liver microsomal enzymes such as alcohol and anticonvulsant agents
- Paracetamol excretion may be affected, and plasma concentrations altered when given with probenecid

Please inform your doctor or pharmacist if you are taking:

- flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (high anion gap metabolic acidosis) that must have urgent treatment and which may occur particularly in case of severe renal impairment, sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), malnutrition, chronic alcoholism, and if the maximum daily doses of paracetamol are used.
- Colestyramine reduces the absorption of paracetamol if given within 1 hour of Paracetamol.

The following interactions with pseudoephedrine have been noted:

Antidepressant medication e.g. tricyclic antidepressants and monoamine oxidase inhibitors (MAOIs) – may cause a serious increase in blood pressure or hypertensive crisis.

Concomitant administration of pseudoephedrine hydrochloride-containing products and MAOIs (or within two weeks of stopping of MAOI) may lead to hypertensive crisis.

- Concomitant use of this medication with sympathomimetic agents (such as decongestants, appetite suppressants and amphetamine-like psychostimulants) which interfere with the catabolism of sympathomimetic amines, may occasionally cause a rise in blood pressure.
- Pseudoephedrine-containing products may antagonise the effect of certain classes of antihypertensives (e.g. beta blockers, methyl-dopa, reserpine, debrisoquine, guanethidine)

d. Pregnancy and lactation:

This product should not be used during pregnancy or while breastfeeding without consulting your doctor.

Safe use of Pseudoephedrine in pregnancy has not been established despite widespread use over many years. Caution should be exercised by balancing the potential benefit of treatment to the mother against any possible hazards to the developing fetus.

Pseudoephedrine is excreted in breast milk in small amounts but the effect of this on breast fed infants is unknown.

e. Driving and using machines:

Patients should be advised not to drive or operate machinery if affected by dizziness.

Possible Adverse Reactions

Stop using this product and consult your doctor immediately if:

Paracetamol:

- In a very rare cases you may experience, thrombocytopaenia, Anaphylaxis, Cutaneous hypersensitivity reactions including among others, skin rashes, angioedema, Stevens Johnson syndrome and Toxic Epidermal Necrolysis, Bronchospasm in patients sensitive to aspirin and other NSAIDs. Hepatic dysfunction.

Pseudoephedrine HCl:

- Nervousness, difficulty sleeping, dizziness, dry mouth, nausea and vomiting, may occasionally occur. Rare reactions may include hallucinations.
- Tachycardia, palpitations, increased blood pressure (increase in systolic blood pressure has been observed, at the therapeutic doses the effects of Pseudoephedrine on blood pressure are not clinically significant), rash, allergic dermatitis (such as bronchospapsm and angioedema).
- Uncommon reactions such as agitation, restlessness, dysuria, urinary retention (most likely to occur in those with bladder outlet obstruction such as prostatic hypertrophy).

Overdose

Seek medical advice immediately in the event of overdose even if symptoms of overdose are not present.

Paracetamol:

Paracetamol overdose may cause liver failure which can lead to liver transplant or death. Acute pancreatitis has been observed with hepatic dysfunction. Immediate medical management is required in the event of overdose, even if symptoms of overdose are not present.

Administration of N-acetylcysteine or methionine may be required.

Pseudoephedrine:

Pseudoephedrine overdose may result in symptoms due to central nervous system and cardiovascular stimulation.

e.g. excitement, restlessness, hallucinations, hypertension and arrhythmias. In severe cases, psychosis convulsions, coma and hypertensive crisis may occur. Serum Potassium levels may be low due to extracellular shifts in Potassium.

Treatment should consist of standard supportive measures.

Beta blockers should reverse the cardiovascular complications and the hypokalemia.

How to store Panadol Sinus?

Store below 30° C.

Pack size: 24's (2 blisters x 12 caplets)

This product is protected in a sealed blister. Do not use if blister or foil is broken.

THIS IS A MEDICINE

- **Medicine is a product which affects your health, and its consumption contrary to instructions is dangerous for you.**
- **Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicine.**
- **The doctor and pharmacist are experts in the use of medicines, its benefits and risks.**
- **Do not by yourself interrupt the period of treatment prescribe for you.**
- **Do not repeat the same prescription without consulting your doctor.**

KEEP MEDICINE OUT OF REACH OF CHILDREN

Council of Arab Health Ministers
Union of Arab Pharmacists

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Do not use this medicine after the expiry date which is stated on the carton and Blister. The expiry date refers to the last day of that month.

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